



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,537	03/29/2005	Jean Paul Remon	50304/070001	4574

21559 7590 07/28/2008
CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

WESTERBERG, NISSA M

ART UNIT	PAPER NUMBER
----------	--------------

1618

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

07/28/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No. 10/529,537	Applicant(s) REMON ET AL.	
	Examiner Nissa M. Westerberg	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19 - 24, 27, 28, 30 - 37 is/are pending in the application.
- 4a) Of the above claim(s) 32 - 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19 - 24, 27, 28, 30, 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments and amendment, filed May 28, 2008, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

Art Unit: 1618

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 19, 20 and 23 – 31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-Shalom (WO95/22962). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed February 28, 2008 and those set forth below. Due to the amendments to the claims, this rejection is now applied to claims 19, 20, 23, 24, and 27 – 31.

Applicant traverse this rejection on the grounds that the matrix of the inner core includes a crystalline polyethylene glycol (PEG) polymer with at least one non-ionic emulsifier, which has at least one domain that is compatible with the crystalline PEG. The preferred emulsifier is PEG stearate and no other embodiment of the matrix is described by Bar-Shalom. The excipient of the inner core does not include crystalline PEG and thus there is no need for the amphiphilic material of amended claim 19 to be restrictively selected such that the amphiphilic material is dispersible in a crystalline PEG. The amount of cellulose derivative in Example 2 cited by the Examiner of 3% by weight is lower than the range claimed by Applicant and that significant amounts of starch are also present.

These arguments are not deemed to be persuasive. While there is support in Example 1 of the instant application for the amendment to the composition of the excipient in the inner core from “comprising” to “consisting of”, the overall language of the claim is still open. For example, item (b) of claim 19 reads the “inner core fills said outer layer and comprises”. The presence of starch is not excluded from the claims of the instant application and therefore the PEG polymer need not be removed to arrive at the composition recited in the instant claims. While the disclosure of Bar-Shalom discloses a narrower genus of amphiphilic materials than that claimed by Applicants, the disclosure of Bar-Shalom still falls within the scope of the claims of the instant application. While the amount of the cellulose derivative in the cited example falls outside of the range claimed by Applicant, Bar-Shalom does disclose that the cellulose derivative, one type of release modifier, will typically be present in the composition in an amount of about 0.1-10% based on the weight of the matrix (p 7, ln 7 – 17). Overlapping ranges are *prima facie* obvious (see MPEP 2144.05) and optimization of the amounts of such ingredients in these compositions is part of routine experimentation and optimization to an artisan of ordinary skill in the art. Therefore, the range disclosed by Bar-Shalom for the amount of cellulose derivative present does render obvious the range of this ingredient claimed by Applicant.

5. Claims 19, 21 and 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-Shalom as applied to claims 19, 20, 23, 24, and 27 – 31 above, and further in view of Santus et al. (US 5,503,843). This rejection is MAINTAINED.

Applicant traverses this rejection on the grounds that the amendments to claim 19 distinguish the claims over the cited prior art and that the teachings of Santos in regards to plasticizers fail to remedy the deficiencies of Bar-Shalom.

This not found to be persuasive. As discussed above, the amendments to claim 19 does not distinguish the claimed invention over the cited prior art. The disclosure of Santos et al. provides additional compounds with the same functional and does remedy the deficiencies of Bar-Shalom which do exist in regards to compounds with a glyceride portion and PEG ester portion.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW

Application/Control Number: 10/529,537
Art Unit: 1618

Page 7